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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,313	07/05/2000	Susan Barnett	PP01631.101	4221
27476 7590 09/08/2010 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY- X100B P.O. BOX 8097 Emeryville, CA 94662-8097				
EXAMINER				
ANGELL, JON E				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
09/08/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/610,313

**Applicant(s)**

BARNETT ET AL.

**Examiner**

J. E. ANGELL

**Art Unit**

1635

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2010.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 and 43-53 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-5-11, 19-21, 39, 52 and 53 is/are rejected.  
7) ☒ Claim(s) 2-4, 12-18, 22-38, 40 and 43-51 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date 6/23/10  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Action is in response to the communication filed on 6/23/2010.

The amendment filed 6/23/2010 is acknowledged and has been entered.

Claims 1-40, 43-53 are currently pending in the application and are addressed herein.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 6/23/2010 is acknowledged.

The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 5-11, 19-21, 39, 52 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16-22, 30-32 of U.S. Patent No. 7,211,659, essentially for the reasons of record. As previously indicated, although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The instant claims are drawn to an expression cassette comprising a polynucleotide sequence operably linked to a promoter, wherein the polynucleotide sequence has at least 90% identity to the polynucleotide sequence presented in SEQ ID NO: 30, SEQ ID NO: 31 or SEQ ID NO: 32. It is noted that the word "has" is synonymous with "comprising". SEQ ID NO: 9 of the '659 patent has at least 90% identity with SEQ ID NO: 30, SEQ ID NO: 31 and SEQ ID NO: 32 (e.g., it has 99.2% identity with SEQ ID NO: 32). Furthermore, claim 1, 16-22 and 30-32 of the '659 patent are similar to the instant claims, but drawn to SEQ ID NO: 9. SEQ ID NO: 9 is at least 90% identical with SEQ ID NO: 30, SEQ ID NO: 31 or SEQ ID NO: 32, the indicated claims of the '659 patent comprise embodiments within the scope of the instant claims. Therefore, the instant claims are unpatentable on the ground of nonstatutory obviousness-type double patenting over claims 1, 16-22, 30-32 of U.S. Patent No. 7,211,659.

***Response to Arguments***

3. Applicant's arguments filed 6/23/2010 have been fully considered but they are not persuasive. Applicant argues that a two-way obviousness analysis is required because the pending application and the later filed application (now the '659 patent) could not have been filed at the same time and that there has not been an intentional delay in prosecution of the instant claims.

4. This is not persuasive. Applicants are respectfully reminded that MPEP 804 states:

If the patent is the later filed application, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application *and* there is administrative delay. *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998)... In the absence of administrative delay, a one-way test is appropriate. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)... Unless the record clearly shows administrative delay by the Office and that applicant could not have avoided filing separate applications, the examiner may use the one-way obviousness determination and shift the burden to applicant to show why a two-way obviousness determination is required... in *In re Emert*, 124 F.3d 1458, 44 USPQ2d 1149 (Fed. Cir. 1997), the court found that the one-way test is appropriate where applicants, rather than the Office, had significant control over the rate of prosecution of the application at issue. In support of its finding that the applicants were responsible for delaying prosecution of the application during the critical period, the court noted that the applicants had requested and received numerous time extensions in various filings. More importantly, the court noted, after initially receiving an obviousness rejection of all claims, applicants had waited the maximum period to reply (6 months), then abandoned the application in favor of a substantially identical continuation application, then received another obviousness rejection of all claims, again waited the maximum period to reply, and then again abandoned the application in favor of a second continuation application substantially identical to the original filing.

In the instant case, the record does not clearly show administrative delay by the office and, furthermore, Applicant had significant control over the rate of prosecution of the pending application. For instance, Applicant requested and received numerous extensions of time including fifteen extensions of time and four requests for continued prosecution (RCE). Therefore, Applicant's argument is not persuasive.

### ***Claim Objections***

5. Claims 2-4, 12-18, 22-38, 40, 43-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/  
Primary Examiner, Art Unit 1635